ISO 9001 Auditing Practices Group

Guidance on:

<u>Effective Use of ISO 19011</u>

Content

INTRODUCTION

ISO 19011:2018 *Guidelines for auditing management systems* provides guidelines for first, second and third-party auditing of management systems. The standard contains guidelines relating to managing an audit program, auditing methods and auditor competence.

Although its content is not mandatory, the standard is the foundation for management system audits. It is specifically referenced in many management systems and sector scheme documents (see the Note in ISO 9001:2015, subclause 9.2 Internal audit, as an example). The guidance is also useful for other audits such as supplier assessments and to evaluate process effectiveness for regulatory compliance. Over the years many professional auditors have been trained according to the previous or current versions of ISO 19011.

ISO 19011 is considered in all the ISO 9001 Auditing Practice Group (APG) papers, with more emphasis in those in the Auditing General section that focus on the audit process. While the APG strives to ensure that the guidance provided in the APG's papers is aligned with the audit fundamentals presented in ISO 19011, the reader should consult ISO 19011 to get the original guidance. In this paper an overview of ISO 19011:2018 is presented, to draw an auditor's attention to the features of ISO 19011:2018, and to remind the auditor of the importance of making effective use of the standard.

ISO 19011:2018 OVERVIEW

The guidance given in the standard is intended to be flexible and its application can differ according to the size, nature and complexity of an organization.

Consistent with the intent for the standard to be universally applicable, contributors to its development represented multiple industries including aerospace, petroleum, medical devices, telecommunications, service and general manufacturing. In addition, experts in different management system disciplines, such as environmental, road traffic safety, occupational health and safety, also contributed. This ensured that the standard's content is generic and applicable to any kind of management system and organization.

In the conformity assessment context and for third party auditors, ISO 19011 provides the guidelines for the audit process and the management of the audit program. In the development of the standard, particular attention was given to ensure the text was aligned with the ISO/IEC 17021 series of documents. This serves to reinforce the requirements stated in the Parts of ISO/IEC 17021, specifically those relating to audit and auditor's competence, as defined for each management system standard.

Organizations should use the guidelines to the extent appropriate to their needs and relevance to their own working practices.

As previously mentioned, ISO 19011 is referenced in a Note in ISO 9001, and other management system standards. Such Notes should not be misconstrued as a requirement. Therefore, and particularly in the context of an ISO 9001 audit, an auditor may not cite a requirement or raise nonconformities against ISO 19011, as its application by the organization is not mandatory.

Third party auditors should keep up to date with revisions to the standard and incorporate any changes and improvements in their audit process (the 2018 edition is the third edition). As with any other reference document it should be kept readily available for consultation when needed.

The standard is divided into a number of clauses, as described in the following:

Principles of auditing

An auditor should be familiar with the 7 principles of auditing and apply them to the audit process. They define a compass that guides auditors' behaviour and conduct to ensure professionalism and objectivity. Consistent with enhanced consideration given to the concept of risk across the entire spectrum of management system standards, the risk-based approach to auditing was added to the list for ISO 19011:2018. The principles are:

- **Integrity**
- **Fair presentation**
- **Due professional care**
- **Confidentiality**
- **Independence**
- **Evidence-based approach**
- **Risk-based approach**

Application of the principles of auditing helps to ensure that audits are conducted with the highest standards of integrity, that they are based on consideration of risk and verifiable evidence, and that they achieve their intended objective.

Managing an audit program

Clause 5 of the standard gives guidance on the audit program management function that an auditor needs to reference when auditing the internal audit requirements.

Individuals having responsibility for the management of an audit program should ensure that:
- The audit program is established and planned
- Risks and opportunities on the audit program are identified
- Audit program objectives are defined
- The competence of an audit team matches the audit scope and objective for each audit in the audit program
- Adequate resources are available for all the audits in the audit program
- Individual audits are monitored for evaluation and improvement of the audit program

It is important to note that management of an audit program is not the purview of an individual auditor. Managing an audit program must be distinguished from planning and conducting audits, as they are two separate and unique processes (however, in some small organizations, they may both be conducted by the same person).

Performing an audit

ISO 19011 provides guidance on planning audits, conducting audits and reporting on audits. There is helpful information on multiple topics including:
- **Roles and responsibilities of the audit team**
- **Conducting the opening and closing meetings**
- **Reviewing documented information**
- **Collecting and verifying evidence**
- **Audit findings**
- **Audit reporting**

In some instances, more specific details and additional guidance are found in the Annex to ISO 19011.

Competence and evaluation of auditors

Competence is defined in ISO 9000:2015 as "ability to apply knowledge and skills to achieve intended results". The guidance in ISO 19011 on the competence and evaluation of auditors emphasizes the importance of team competence as well as that of the individual. Auditors should possess the knowledge and skills necessary to achieve the intended results of the audits. Auditors should possess both generic and sector-specific knowledge and skills. Audit team leaders should have the additional competence to provide leadership to the audit team.

Competence should be determined through a process that considers an auditor's personal behavior and their ability to apply the knowledge and skills gained through education, work experience, auditor training and audit experience.

Some competence criteria for auditors may vary depending on the type of audit being conducted (such as a third party certification audit) and the industry or discipline being audited. For third party auditors, generic competence criteria requirements are defined in ISO/IEC 17021-1, clause 4.3, with specific criteria being defined in complementary documents for a particular management system standard or sector (e.g. ISO/IEC 17021-3 for quality management systems). However, individual auditors should be aware of the content of ISO/IEC 17021-1, clause 4.3, so that they can maintain, improve and work within the limits of their professional competence.

Auditor competence should be monitored and periodically re-evaluated for improvement.

Annex A – Additional guidance

ISO 19011: 2018 has extensive information in its Annex on multiple topics; given below is a brief summary of a few.

Audit methods
An overview of remote audit practices (as distinct from on-site audits) is presented and provides general guidance on human versus non-human interactive audit practices. (The guidance was used as an input for the development of the APG paper on Remote Audits).

Sampling
There are three separate sampling methods discussed. The first speaks in general terms about selection methods, sample size, composition of population and methods of evaluating. The second covers aspects of judgement-based sampling wherein the expertise of the auditor, the complexity of processes and other human factors are discussed. The last sampling method focuses on statistical sampling based on probability theory.

Auditing context
This topic reflects the introduction of the concept of the "context of the organization" into several management system standards over recent years. Guidance is presented on how to verify conformity to these requirements.

Life cycle
Life cycle is an example of a set of requirements that are only relevant in organizations that have products with a limited or defined life. There are often specific requirements relating to design, to

material traceability, to end of life treatment, etc. Guidance is provided on how to audit the requirements.

Supply chain
Auditing of suppliers is generally termed "2nd party" audits. A brief overview of considerations when planning such audits is provided.

Audit findings
The guidance covers determining the audit findings, recording both conformities and nonconformities, and dealing with findings related to multiple criteria.

As mentioned in ISO 19011: "This guidance should be adapted as appropriate to the scope, complexity and scale of the audit program".

For further information on the ISO 9001 Auditing Practices Group, please refer to the paper: Introduction to the ISO 9001 Auditing Practices Group.

Feedback from users will be used by the ISO 9001 Auditing Practices Group to determine whether additional guidance documents should be developed, or if these current ones should be revised. Comments on the papers or presentations can be sent to the following email address: charles.corrie@bsigoup.com.

The other ISO 9001 Auditing Practices Group papers and presentations may be downloaded from the web sites:

www.iaf.nu
https://committee.iso.org/home/tc176/iso-9001-auditing-practices-group.html

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